Memorandum

DATE: April 25, 2011

TO: The Record

FROM: [redacted]
DCD/PDLB

SUBJECT: P890003/S209 – Lead Review
Application SW Model Number SW0007 for Reveal ICM/Patient Assistant, Carelink Home Monitor and CardioSight Monitor
Medtronic

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RECOMMENDATION: APPROVED

BACKGROUND

The following is the lead review of a premarket approval (PMA) application supplement for updates to Medtronic's Reveal 2090 Application Software Model SW007 for use with the Medtronic Reveal Implantable Cardiac Monitor (ICM) System. A 510(k) has also been submitted for changes to the Reveal ICM/Patient Assistant, K103764.

The application was received on Dec 22, 2010. This submission is a 180-day supplement.

REVIEW TEAM

The following CDRH individuals contributed to the review of this submission:

[redacted], ODE/DCD/PDLB - lead review
[redacted], ODE/DCD/CEMB – animal test review
[redacted], ODE/DCD/PDLB – clinical review

INDICATIONS FOR USE

The indication for use remained unchanged from the previous submission for Model SW007 version 1.1 (P890003/S148) and was not repeated in the submission. The currently marketed released version of application software is 7.0 (P890003/S151).

DEVICE DESCRIPTION

The device description from the submission:

The Reveal DX and Reveal XT Insertable Cardiac Monitors were originally cleared on 21 November (K071655 and K071641). Software Model SW007 version 1.0 which supports Reveal DX and Reveal XT was approved on 16 October 2007 (P890003/S123). The Reveal XT Model 9529 and Reveal DX Model 9528 enhancements submission was cleared via K082475 on 7 November 2008. The corresponding version 1.1 was approved on 14 October 2008 (P890003/S148). The Model SW007 version 7.1 builds off of the version 1.1 software. Version 7.1 contains all the same functionality as version 1.1 with additional minor enhancements. It should be noted that the currently market released version of application software is 7.0, which only included migration to the (b) (4) operating system (P890003/S151, approved 11 December 2008). The version 7.1 software includes minor user interface changes and a (b) (4) download which will upgrade the firmware in the Reveal XT (Model 9529) and Reveal DX (Model 9528) Insertable Cardiac Monitor. A separate 510(k) will be submitted for changes to the Reveal XT and Reveal DX devices.

The Model SW007 version 7.1 software operates on the Medtronic CareLink Programmer Model 2090.

The Model 2490G Carelink Home Monitor, Model 2491 DDMA and Model 2020A CardioSight Reader were submitted and approved on 08 July 2008 (P890003/S141).

CHANGES

The following changes are planned:

Device	Enhancements/Upgrades
Application Software Model SW007	A. Enhancement to the viewing of stored episodes.
	B. Selectable SW Filter applied to stored waveforms
	C. Increased control over detection parameters to allow for more customizable care.
	D. Real-time on screen R-wave amplitude display.
	E. Increased printing options.
	F. Calibration pulse added to stored episodes.
	G. New selectable parameters relating to algorithm changes in device.
	H. Symptom “S” mark on the cardiac compass report.
	I. Additional markers added for Asystole, FVT, and VT rejection due to noise.
	J. Enhancement download into Reveal Model 9529 (Reveal XT) and 9528 (Reveal DX) ICM.

Device	Enhancements/Upgrades
	K. Addition of Full View software brand
	L. Secure Delete of Temporary files

In the submission, other changes were included. However, these changes are for the firmware for the ICM devices and packaging and are submitted under a separate 510(k). A sponsor email was received which stated that this PMA supplement is primarily to support functional changes to the device and to improve some programmer user interfaces.

SOFTWARE

Version:	Model SW007 version 7.1		
Level of Concern:	MAJOR (This is appropriate for this type of device and is consistent with other similar devices)		
		Yes	**No**
Software/Firmware description: The Model SW007 Software is used with the Medtronic CareLink Programmer Model 2090 to support the Reveal DX Model 9528 and Reveal XT Model 9529 Insertable Cardiac Monitors. The Medtronic CareLink Programmer is used for in-office follow-ups and to view episodes for the Reveal DX and Reveal XT ICM. The programmer will allow adjusting programmable parameters, storage of device and patient information, viewing collected data, clearing stored data, printing reports and viewing real-time ECG signals. The Medtronic Model 2090 CareLink Programmer will communicate with the ICM via a programming head using Telemetry B communications. Telemetry B communications will be initiated without the use of a magnet. Operational Environment: Programming language: (b) (4) Hardware platform: Medtronic CareLink Programmer Model 2090 Operating system: (b) (4) Use of Off the Shelf components: The Medtronic Model 9986 Desktop BOSS (version 1.6, P890003/S117 approved 3 May 2007) base operating system software is available through the Model SW007 Software to allow updating of the 2090 CareLink Programmer system, as needed. The Model SW007 Software requires the use with a minimum of the Model 9986 BOSS, version 2.4 (targeted for submission to FDA by 24 December 2010 under PMA P890003).	X	
Device Hazard Analysis: The sponsor has included the risk analysis information in attachment 3 of their submission. The sponsor has included the risk management report in this section. The risk management report summarizes the risk management activities performed for the Reveal SW Upgrade system. The system was reviewed for potential hazardous scenarios that could result from the new feature enhancements or modifications to the baseline legacy systems. The hazards identified are consistent with what would be expected for this type of product. A Product/System Characteristics document was not completed because the baseline intended use, purpose, and foreseeable misuse similar to the predecessor Reveal devices. Environment risk, component failure risk, and manufacturing risk were not addressed because the changes do not impact these areas. The risk analysis is appropriate for this type of system. All identified system	X	

Version:	Model SW007 version 7.1		
Level of Concern:	MAJOR (This is appropriate for this type of device and is consistent with other similar devices)		
		Yes	**No**
hazard scenarios have been mitigated or are at an acceptable level of risk.			
Software Requirements Specifications: The sponsor has provided software requirement specifications in this submission. The Reveal XT System specification was attachment 1 in the submission. The software requirements for the Model SW007 Software are in the updated Reveal XT/DX Software requirement specification in attachment 2 of the submission. The requirements appear to adequately define the software functionality associated with the Reveal System. The requirements describe the user requirements that the system must meet and the description of the system features and components that satisfy these requirements. The software requirement specification defines functionality, response to valid and invalid input, and external interfaces.		X	
Architecture Design Chart: The sponsor provided the architecture design document CRM Vision Software Architecture Description as attachment 4 in the submission. This document was not updated for the software update. The software architecture document provides a decomposition and analysis of the Model SW007 Software architecture, including rationale supporting the choice of architecture and design strategies used. The sponsor provided information is adequate.		X	
Design Specifications: The sponsor provided description of the software design specification process in the Software Development Plan (attachment 5 of the submission). This document establishes the process to be used during the development of the Reveal SW Upgrade. The Reveal SW Upgrade Software Verification Test Plan was also provided as attachment 6 of the submission. This document outlines overall testing requirements. The sponsor provided information is adequate.		X	
Traceability Analysis/Matrix: The sponsor provided a Software Verification Test Trace Report as attachment 7 of the submission. This document provides traceability between the Software Requirements Specification and the Test Designs. The testing result of all Test Designs is provided in the Reveal SW Upgrade SWVT Test Results Report (attachment 8 of the submission). The sponsor also provided the Reveal XT System Verification Test Plan (attachment 9 of the submission). This information demonstrates that the requirements were tested during verification and the sponsor provided information is adequate.		X	

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		Yes	**No**
Development: The Software Development Plan (attachment 5 of the submission) defines the overall strategic plan and processes to be followed for verification activities. The plan included a description of the life cycle model process, coding practices, and software configuration management. The sponsor provided information is adequate.		X	
Verification & Validation Testing: Development plans were written containing the verification and validation testing strategies for the Reveal DX/XT systems and the Model SW007 Software used with the Medtronic CareLink Model 2090 programmer. Details of the plans are described in the following documents: Software Development Plan, submission attachment 5 Software Development and Testing Software Verification Test Plan, submission attachment 6 Reveal Software Upgrade System Verification Plan, submission attachment 9 Reveal Software Upgrade Manuals System Validation Test Plan/Reveal Software Upgrade System Validation Test Plan, submission attachment 10 Test consisting of unit tests and subsystem integration tests were performed. Detailed information regarding the developer's tests is located in the Software Development Plan (submission attachment 5). Requirements based testing was performed at the sub-system level and at the system level. The sub-system verification test was a (b) (4) test the primarily ensures that the fully integrated software operates as prescribed in the software requirements specification. Stress testing and installation testing were also executed. All issues detected during the software verification tests were reported in the Reveal SW Upgrade SWVT Test Results Report (submission attachment 9) System verification testing was performed to ensure that the Reveal DX/XT system operates as intended. The Reveal Software Upgrade System Verification Plan (submission attachment 9) outlines testing requirements. The Reveal XT System Verification Test Report is included as submission attachment 11. The System was also validated to ensure that the system met the needs of the user and the patient. The System Test Plan was included as attachment 10 of the submission. This test plan includes the strategy for manual review(s), system compatibility, installation, and protocol testing for the upgrade scenarios. The Reveal XT System Validation Test Report is included as submission attachment 12. The Test Reports were reviewed and the results look appropriate.		X	

Version:	Model SW007 version 7.1		
Level of Concern:	MAJOR (This is appropriate for this type of device and is consistent with other similar devices)		
		Yes	**No**
Revision level history: The sponsor provided a list of the different software versions used during testing as a part of the SWVT Test Results Report (attachment 8 of the submission). Three versions of the software were tested. The Software Version Description Document was provided as attachment 13 of the submission. The sponsor provided information is adequate.		X	
Unresolved anomalies: The sponsor provided a list of unresolved anomalies as part of attachment 8 of the submission. This list showed one anomaly from the software system test which was deemed acceptable by the sponsor. Telemetry was dropped during the 2090 session with the Reveal device. The lights on the 2090 RF head were amber and lifting/moving the telemetry head did not reestablish telemetry. The chart recorder was still functional and the screens could still be navigated. RF hard keys could still attempt interrogate/program, but no telemetry could be obtained until the session was ended and Find Patient on the desktop was performed. The anomaly was reviewed and the rationale agreed with as there is no patient safety issue. No unresolved anomalies are present after the System Verification Test was performed. In the System Validation Test Report, two anomalies deemed acceptable by the sponsor were listed in section 6.0 Issue Resolution. One anomaly was the same one as identified earlier in this section. The other anomaly was: The following System error occurred during installation of the Desktop 2.4 SW: BSOD 00000050 C1CC7008 00000000 8056EEE6 00000000. This occurred right after the user touched the stylus to screen background during System Driver Installation. A memory dump of the programmer was performed, the power was cycled and SW continued without issue. The anomaly was reviewed and the rationale agreed with as there is no patient safety issue. The issue occurs during software installation and no patient sessions are active during software installation. One item noticed was that the submission stated that there were no unresolved anomalies found during system validation testing. However, the system validation test report did describe two anomalies deemed acceptable. Upon clarification from the sponsor, they considered them to be resolved even though a fix has not been implemented.		X	

also reviewed the software changes from a clinical perspective and initially deemed some of the changes were not supported by performance data and suggested that these changes might be inadequately characterized for safety and effectiveness. These

changes were initially noted as a major deficiency. However, upon further discussion and the conclusion that the PMA supplement does not propose any functional changes to the implant device; the deficiencies are no longer relevant for this PMA supplement. This is a summary of ' review memo dated March 8, 2011, updated March 11, 2011.

All other software changes were deemed acceptable in the initial clinical review.

HUMAN FACTORS

reviewed the Human Factors testing and initially noted a major deficiency regarding unfavorable results. This deficiency was addressed interactively and was resolved. ' review memo states the initial deficiency, the response from the sponsor, and the final conclusion which resolved the deficiency.

There are no further issues with Human Factors.

ANIMAL STUDIES

A GLP canine study was performed to validate the performance of the Reveal Software Upgrade for the Reveal insertable cardiac monitor (ICM). The study was reviewed by and was deemed approvable in her approval memo dated March 3, 2011.

also reviewed the study from a clinical perspective and initially deemed the study to be inadequate and noted a major deficiency. However, upon further discussion and the conclusion that the PMA supplement does not propose any functional changes to the implant device; the deficiency is no longer relevant for this PMA supplement. This is also a summary of ' review memo.

There are no further issues in Animal Studies.

LABELING

The Clinician Manuals submitted were updated to reflect proposed changes and to incorporate additional edits. The manuals were reviewed and are deemed acceptable.

also reviewed the Clinician Manuals and deemed the manuals acceptable. In the event that the manual must be changed to accommodate the 510(k) changes under review, the labeling must be updated and resubmitted for FDA review. This is also a summary of ' review memo.

There are no further issues with the labeling. The sponsor has also submitted the Clinician Manual for approval in the separate 510(k).

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Manufacturing (unchanged)
- Packaging (unchanged)
- Sterilization (unchanged)
- Biocompatibility (N/A)
- Statistical (N/A)
- Electrical Safety (N/A)
- Mechanical Safety (N/A)

CONCLUSION

As discussed above, the consensus of the review team is that the safety and effectiveness of Medtronic's Reveal 2090 Application Software Model SW007 could be established.

Changes for the firmware for the ICM devices and packaging are submitted under a separate 510(k) (K103764) and were not evaluated in this submission. This PMA supplement is primarily to support functional changes to the device and to improve some programmer user interfaces as clarified by the sponsor.

RECOMMENDATION

I recommend that the sponsor receive an **approvable** letter.

(b) (5) Date

NOTE: An electronic copy of this file has been stored in the (b) (5) "CDRH – Division of Cardiovascular Devices > Branch-Specific Folders > PDLB > PMAs > P890003 – Medtronic Reveal ICM System > S209 – Application SW Model SW007 ver 7.1"